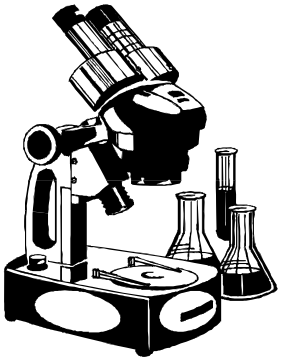

CLIA BITS

North Dakota Department of Health
Division of Health Facilities

Fall 2002

First Case of Vancomycin-resistant Staph in U.S.

An article was recently published in MMWR regarding Vancomycin-resistant Staphylococcus. This article describes the first documented case of infection caused by vancomycin-resistant S. aureus in a patient in the United States. The bacteria was isolated from a 40-year-old Michigan resident with diabetes, peripheral vascular disease and chronic renal failure.

The complete article can be found in the July 5, 2002 MMWR report Vol.51/No.26 and at www.cdc.gov/mmwr/preview/mmwrhtml/mm5126a1.htm.

CLIA Report to Congress

The annual Report to Congress about the CLIA validation review of the six accreditation organizations approved under CLIA can now be viewed on the Centers for Medicare and Medicaid Service (CMS) website. The CLIA report appears in the last section of the CMS Financial Report. The report can be accessed at: www.cms.hhs.gov/contractors/cfo.

Hearing Decision Website

The CLIA Hearings Index Workgroup recently announced the posting of the list entitled "CLIA-Related Hearing Decisions" on the following CMS website: www.cms.hhs.gov/clia/hearinggroup.asp. The website contains a list of hearing decisions related to the CLIA program.

CLIA and Hospital Compliance

The following was released in the form of a memo by CMS to alert state survey agencies of the effect a CLIA sanction could have on a Medicare-certified hospital.

The laboratory services condition of participation at 42 CFR section 482.27 is among the conditions of participation that hospitals must meet. Therefore, a hospital laboratory needs a CLIA certificate covering the full range of testing required by the hospital or needs to have an agreement with a CLIA-certified laboratory to provide this testing. If the hospital's CLIA certificate or the contracted laboratory's CLIA certificate is limited, suspended or revoked or if the laboratory is subject to a cancellation of Medicare or Medicaid approval, the hospital is not in compliance with the laboratory services condition of participation and is subject to enforcement action.

Attention MLA 750 and 800 Users

The North Dakota Department of Health CLIA program is requesting that all laboratories performing coagulation on the MLA 750 or 800 and using DADE reagents to please call DADE technical support. There has been a change in which ISI value should be used. It is each laboratory's responsibility to contact DADE technical support and implement appropriate procedural changes if indicated.

Gonorrhea Test Kits Recalled by Abbott Laboratories

The Food and Drug Administration (FDA) recently announce that Abbott Laboratories Inc. has initiated a worldwide recall of 32 lots of laboratory kits used to diagnose gonorrhea. The kits have been shown to be unreliable because they may give false negative results. These test kits were distributed to hospitals and laboratories from Jan. 11 to June 24, 2002. Abbott voluntarily recalled the gonorrhea test kits after learning through routine internal testing that certain lots did not meet specifications and, as a result, could report positive test results as negative.

The following lots have been recalled: 84073M400; 84075M400; 84142M300; 84146M300; 85487M200; 87007M400; 87103M400; 87243M100; 87377M200; 87899M200; 87905M200; 88097M300; 88105M300; 88107M300; 88439M200 and 88439M201. Patients who received a negative test result with test kits from these lots may need to be retested.

The FDA News press release can be found at: www.fda.gov/bbs/topics/NEWS/2002/NEW00832.html.

Don't judge each day by the harvest you reap but by the seeds that you plant.

Robert Louis Stevenson

Applicability of CLIA to Monitoring the Organs Before Recovery and Transplantation

Section 353 of The Public Health Service Act sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Laboratories are facilities that perform biological, microbiological, serological, chemical, immunological, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings.

The law and regulations address laboratory testing that provides information concerning the health of "human beings." While the testing sample is obtained from a clinically deceased individual, the testing is performed to provide information for the treatment of a living patient who is in need of an organ transplant. Therefore, any laboratory performing testing on a potential cadaveric organ donor for the purpose of testing the viability of, or monitoring or maintaining the organ for, transplantation must comply with the CLIA requirements in 42 CFR Part 493.

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